

REMARKS

Claims 19-37 are currently pending in the present application.

Claims 19 and 30 have been amended herein to specify that the claimed processes require the providing of an aqueous mixture of a polysaccharide biopolymer. The amendments to claims 19 and 30 are supported by the Specification, for example, at page 5, lines 17-28; and in the Examples. Claim 34 has been amended to correct a typographical error in the recited dependency. No new matter has been introduced. A complete listing of all claims ever presented is included herein in accordance with 37 C.F.R. §1.121(c). Entry of the amendments to claims 19, 30 and 34 is therefore proper and respectfully requested.

In Paper No. 8, the Examiner rejects claim 34 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. Specifically, the Examiner contends that claim 34 is redundant of claim 31, from which it depends.

Applicants have amended claim 34 to correct the dependency recited therein. Claim 34, as amended, depends from claim 30. Claim 30 is directed to a process for preparing a crosslinker-free composition. Claim 34 is now directed to a crosslinker-free composition prepared by the process of claim 30.

Applicants respectfully submit that claim 34 is no longer redundant. Accordingly, reconsideration and withdrawal of the Examiner's rejection under 35 U.S.C. §112, second paragraph is requested.

In Paper No. 8, the Examiner rejects claims 19-37 under 35 U.S.C. §103(a), as being unpatentable over U.S. Pat. No. 5,990,381 of Nishihara (hereinafter referred to as "Nishihara"). Specifically, the Examiner contends that Nishihara discloses a biomedical material comprising shark-derived collagen, and methods of making the same. The Examiner also notes that Nishihara discloses a process wherein an aqueous calcium hydroxide solution is added to a collagen solution to obtain an aqueous suspension, which is then filtered and freeze-dried. On this basis, the Examiner argues that the claimed invention is *prima facie* obvious and that the burden to prove otherwise has shifted onto Applicants.

Applicants strenuously, but respectfully, traverse the Examiner's rejection and the arguments and contentions in support thereof for the following reasons.

To begin with, Applicants' claimed invention, as amended, is directed to processes for preparing a crosslinker-free composition, which comprise: (a) providing an aqueous mixture of a *polysaccharide* biopolymer, wherein the aqueous mixture has a viscosity of from 1,000 mPas to 100,000 mPas; (b) combining a precipitant with the aqueous mixture to form a crosslinker-free biopolymer composition; and (c) dewatering the crosslinker-free biopolymer composition to form a crosslinker-free three-dimensional structure.

Nishihara is directed to the production of materials comprising shark-derived collagen. (*See*, Nishihara, Abstract). As indicated in Nishihara, collagen is a fibrous protein. (*See*, Nishihara, col. 3, lines 40-41). Nishihara does not teach or suggest the claimed process wherein an aqueous mixture of a polysaccharide biopolymer is combined with a precipitant and dewatered. The reference to chitosan cited by the Examiner simply mentions that in the preparation of a wound cover or artificial skin, the inventive collagen layer may be laid upon another layer of wound covering which comprises other components, such as chitosan. (*See*, Nishihara, col. 7, lines 20-29). There is no teaching or suggestion which would motivate one of ordinary skill in the art to modify the teachings of Nishihara to arrive at the claimed invention. Nishihara does not suggest substituting "the other components" for the specifically taught collagen.

It is well-settled that in order to establish a *prima facie* case of obviousness based upon a single reference, and thus shift the burden of proving non-obviousness onto Applicants, the Examiner MUST satisfy each of the following three criteria: (1) the reference must contain a teaching or suggestion which would motivate one of ordinary skill in the art to modify the reference as suggested by the Examiner (it is not sufficient to say that the reference can be modified without a teaching in the cited reference to suggest the desirability of such a modification); (2) there must be a reasonable expectation of success; and (3) the reference must teach or suggest each and every element of Applicants' claimed invention. The teaching or

suggestion to modify the cited art and the reasonable expectation of success must both be found in the prior art and not in Applicants' Specification. (See, M.P.E.P. §2143).

Nishihara fails to teach or suggest each and every element of the claimed invention. Specifically, Nishihara fails to teach or suggest the claimed process wherein an aqueous mixture of a *polysaccharide* biopolymer is combined with a precipitant to form a crosslinker-free biopolymer composition. Nor does Nishihara contain any teaching or suggestion which would motivate one of ordinary skill in the art to modify the teachings of the reference, as suggested by the Examiner, in order to arrive at the claimed invention. Finally, given the lack of any suggestion to substitute "the other components" for the taught collagen, it is difficult to envision one of ordinary skill in the art having a reasonable expectation of successfully doing so.

Thus, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness based upon the teachings of Nishihara. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) based upon Nishihara are respectfully requested.

In view of the amendments made herein and the comments set forth above, Applicants submit that all pending claims patentably distinguish over the prior art of record and known to Applicants, either alone or in combination. Accordingly, reconsideration, withdrawal of the rejections and a Notice of Allowance for all pending claims are respectfully requested.

Respectfully submitted,

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